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# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

PAUL BENNETT, On Behalf of Himself and All Others Similarly Situated,		No. 03-CV-12091-RCL
Plain	tiff, )	CLASS ACTION
VS.	)	
ALKERMES, INC., et al.,	)	
Defer	ndants.	
VINCENT RAGOSTA, On Behalf of Himself and All Others Similarly Situated,		No. 03-CV-12184-RCL
Plain	tiff,	CLASS ACTION
vs.	)	
ALKERMES, INC., et al.,	)	
Defer	ndants. )	
[Caption continued on following pa	) ge ]	

SOUTHERN ALASKA CARPENTERS RETIREMENT TRUST'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO BE APPOINTED LEAD PLAINTIFF PURSUANT TO SECTION 21D(a)(3)(B) OF THE SECURITIES EXCHANGE ACT OF 1934 AND FOR APPOINTMENT OF LEAD COUNSEL; REQUEST FOR ORAL ARGUMENT

BARRY FAMILY LP, On I All Others Similarly Situate	Behalf of Itself and )	Civil Action No. 03-CV-12243-RCL
•	Plaintiff,	CLASS ACTION
VS.	)	
ALKERMES, INC., et al.,	)	
	Defendants.	
JULIUS AND PHYLLIS W Behalf of Themselves and A Situated,		Civil Action No. 03-CV-12277-RCL <u>CLASS ACTION</u>
	Plaintiffs,	
vs.	)	
ALKERMES, INC., et al.,	)	
	Defendants. )	
DEBRA S. FOLKERTS, Or and All Others Similarly Sit	Behalf of Herself ) uated,	Civil Action No. 03-CV-12386-RCL
	Plaintiff,	<u>CLASS ACTION</u>
VS.	)	
ALKERMES, INC., et al.,	)	
	Defendants.	
JAMES P. SLAVAS, On Be and All Others Similarly Situ		Civil Action No. 03-CV-12471-RCL
	Plaintiff,	CLASS ACTION
vs.	)	
ALKERMES, INC., et al.,	)	
	Defendants. )	

#### I. INTRODUCTION

The Southern Alaska Carpenters Retirement Trust ("Movant" or "Proposed Lead Plaintiff"), which purchased on the open market or otherwise acquired Alkermes, Inc. ("Alkermes" or the "Company") securities between April 22, 1999 and July 1, 2002 (the "Class Period"), hereby moves this Court for an order granting its Motion to Be Appointed Lead Plaintiff Pursuant to §21D(a)(3)(B) of the Securities Exchange Act of 1934 and for Appointment of Lead Counsel.

This motion is brought pursuant to §21D of the Securities Exchange Act of 1934 ("Exchange Act") on the grounds that Movant has timely filed and is the "most adequate plaintiff." In addition, Movant seeks the Court's approval of its selection of Patrick J. Coughlin and Jeffrey W. Lawrence of Milberg Weiss Bershad Hynes & Lerach LLP ("Milberg Weiss") as lead counsel and the appointment of Moulton & Gans, P.C. ("Moulton & Gans") as liaison counsel for the class pursuant to §21D(a)(3)(B)(v), 15 U.S.C. §78u-4(a)(3)(B)(v).

Presently pending in this district are six related securities class action lawsuits:

Abbreviated Case Name	Case Number	Date Filed
Bennett v. Alkermes , Inc., et al.	03-12091-RCL	10/29/03
Ragosta v. Alkermes, Inc., et al.	03-12184-RCL	11/06/03
Barry Family LP v. Alkermes, Inc., et al.	03-12243-RCL	11/13/03
Waltzer v. Alkermes , Inc., et al.	03-12277-RCL	11/17/03
Folkerts v. Alkermes, Inc., et al.	03-12386-RCL	11/25/03
Slavas v. Alkermes, Inc., et al.	03-12471-RCL	12/09/03

The plaintiffs in each of these actions allege violations of the Exchange Act and Rule 10b-5 promulgated thereunder, on behalf of those who purchased on the open market or otherwise acquired Alkermes securities during the Class Period. Movant submits this memorandum in support of its motion for: (a) the appointment of Movant as pead plaintiff; and (b) approval of Movant's choice of

lead counsel and liaison counsel to represent the class in the consolidated actions.<sup>1</sup> Movant suffered approximate losses of \$88,388, which Movant believes constitutes the largest financial interest in the relief sought by the class.

Section 21D of the Exchange Act sets forth the procedure for the selection of lead plaintiffs to oversee class actions brought under the federal securities laws. Specifically, §21D(a)(3)(A)(i) provides that, within 20 days after the date on which a class action is filed under the Private Securities Litigation Reform Act of 1995 ("PSLRA"),

the plaintiff or plaintiffs shall cause to be published, in a widely circulated national business-oriented publication or wire service, a notice advising members of the purported plaintiff class --

- (I) of the pendency of the action, the claims asserted therein, and the purported class period; and
- (II) that, not later than 60 days after the date on which the notice is published, any member of the purported class may move the court to serve as lead plaintiff of the purported class.

15 U.S.C. §78u-4(a)(3)(A)(i).

Further, §21D(a)(3)(B) of the Exchange Act directs the Court to consider any motions by plaintiffs or purported class members to serve as lead plaintiffs in response to any such notice by the later of (a) 90 days after the date of publication; or (b) as soon as practicable after the court decides any pending motion to consolidate any actions asserting substantially the same claim or claims. Under this section of the Exchange Act, the Court "shall" appoint the "most adequate plaintiff" and is to presume that the "most adequate plaintiff" to serve as lead plaintiff is the person, or group of persons, that

Simultaneously with this motion, Movant has moved to consolidate each of the pending related cases.

has either filed the complaint or made a motion in response to a notice ...;

in the determination of the court, has the largest financial interest in the relief sought by the class; and

otherwise satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure.

Section 21D(a)(3)(B)(iii), 15 U.S.C. §78u-4(a)(3)(B)(iii). Movant brings this motion within 60 days of the first published notice, and suffered approximately \$88,388 in losses.

Movant therefore has a substantial financial interest in the relief sought by the class. Movant also satisfies the requirement of Rule 23 of the Federal Rules of Civil Procedure because Movant's claims are typical of the claims of the class, and it will fairly and adequately represent the interests of the class, since its interests are clearly aligned with the members of the class, and it has retained experienced class counsel to represent the class.

Accordingly, Movant is "the most adequate plaintiff," as defined in the PSLRA, and brings this motion seeking to be appointed lead plaintiff.

Movant also seeks the Court's approval of the Proposed Lead Plaintiff's choice of Patrick J. Coughlin and Jeffrey W. Lawrence of Milberg Weiss as lead counsel and Moulton & Gans as liaison counsel to represent the class in the consolidated actions.

#### II. SUMMARY OF ACTIONS

These related class actions allege a common course of conduct by the same defendants in violation of §§10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5. The actions name Alkermes and a number of its senior executives as defendants<sup>2</sup> and are brought on behalf of all persons who purchased or otherwise acquired Alkermes

Richard F. Pops, Robert A. Breyer, David A. Broecker, Michael J. Landine, James M. Frates and James L. Wright are the individual defendants named in each of the complaints.

securities between April 22, 1999 and July 1, 2002 (the "Class Period.") ¶1.³ Each action alleges that defendants sought to artificially inflate the value of their securities through materially false and misleading statements about the Company's New Drug Application ("NDA") to the Federal Drug Administration ("FDA") for Risperdal Consta, allowing defendants to reap insider trading proceeds of over \$43 million and causing the Company to sell \$200 million worth of its own securities. ¶¶6, 8, 13-14, 16-18.

Alkermes is a biopharmaceutical company focused on the development of controlled-release drug delivery technologies and their application to existing or new drug therapies. ¶2. Risperdal belongs to a class of compounds referred to as atypical antipsychotics, used in the treatment of schizophrenia. ¶22. The goal of a successful drug to treat schizophrenia is to inhibit and eliminate the mental, emotional, and behavioral disturbances associated with the disorder, with minimal side effects. ¶27. Risperdal Consta is administered by an intramuscular injection into the deep muscle tissue of the patient. ¶29. If approved by the FDA, Risperdal Consta would represent the first example of a sustained release or "depot" formation for biweekly administration, to mitigate patient compliance issues. ¶23.

Throughout the Class Period, defendants concealed the deficient nature of their manufacturing process and facilities, as well as serious safety issues and adverse side effects associated with use of Risperdal Consta. ¶7. Specifically, on April 22, 1999, Alkermes issued a press release stating that Alkermes and its joint venture partner Janssen Pharmaceutica ("Janssen") were proceeding into Phase III clinical trials of sustained release Risperdal. ¶34. This press release

Unless otherwise indicated, all paragraph references ("¶") are to the complaint filed in Bennett v. Alkermes, Inc., et al., Case No. 03-12091-RCL, on October 29, 2003. Each of the other actions contains similar allegations.

also stated that Alkermes had completed scale-up and Phase III manufacturing activities at the expected commercial scale. *Id.* Defendants, however, concealed the fact that their facilities were wholly unable to commence or maintain commercial scale operations for the manufacture of Risperdal Consta or any other drug product. ¶36. Defendants also concealed quality issues with the Medisorb polymer used in the production of Risperdal Consta manufacturing lots. ¶37. Defendants decided to forego routinely conducting tests for molecular weight on Medisorb polymer lots to conceal the fact that Medisorb polymer production methods resulted in molecular weights with an unacceptably wide variation from lot to lot for use in production of sustained-release drug delivery systems. *Id*.

On February 16, 2000, Alkermes issued a press release announcing the private placement of \$200 million in convertible subordinated notes. ¶39. News of this badly needed financing reassured investors that the Company's products were viable, and Alkermes shares spiked nearly 90% in value in the days following the announcement. ¶40.

On May 19, 2000, defendants filed for the grant of a patent entitled "Method for Preparing Microparticles Having a Selected Polymer Molecular Weight." ¶41. Defendants sought this new patented and proprietary process that would actually complicate the Risperdal Consta manufacturing process in order to conceal quality issues relating to variation in the manufacturing process for the Medisorb polymer. ¶44.

In September 2000, defendants' joint venture partner, Janssen, caused to be published a Review Article entitled, "A Risk-Benefit Assessment of Risperidone for the Treatment of Behavioural and Psychological Symptoms in Dementia." ¶46. The article signaled the acceptability of the safety and efficacy profile of the drug for the treatment of dementia in the elderly. *Id.* While the article was intended to disclose serious Risperdal side effects as a part of a risk-benefit

assessment, it actually concealed serious adverse cerebrovascular side effects in the elderly, contained in one or more Janssen studies cited as references to the article. ¶46.

On September 4, 2001, the Company issued a press release signaling that Alkermes was ready to manufacture Risperdal Consta. ¶50-51. Defendants again concealed that their facilities were, in fact, unable to begin commercial manufacturing of the product at the expected levels. ¶51. In the September 4, 2001 press release, defendants raised broad-based concerns about all antipsychotic medications, but concealed the special safety concerns that would accompany use of Risperdal when formulated using Medisorb technology for sustained release. ¶52.

On October 30, 2001, the Company issued a press release claiming its current manufacturing facility was fully equipped to support launch quantities and to meet early demand projected for long-acting Risperdal. ¶57. Despite these assertions, defendants remained wholly unable to begin commercial manufacturing of the product at all expected levels. ¶58. The October 30, 2001 press release also stated that Alkermes had committed to expand production capacity in exchange for guaranteed financial payments from its joint venture partner Janssen. ¶57. Defendants' claims were false and misleading because they failed to point out that the costs of the expansion project were to be borne entirely by defendants and, after commercialization, were to come out of defendants' royalty revenues. ¶59.

On February 26, 2002, the Company issued a press release announcing the submission of a new drug application ("NDA") for Risperdal Consta by Johnson & Johnson Pharmaceutical Research & Development ("Johnson & Johnson"), which conducted the clinical-development program. ¶61. The press release also stated that the use of Risperdal Consta did not compromise patient safety. ¶¶61-62. This press release was false and misleading since Risperdal Consta cannot

be removed once injected and there is no way to discontinue delivery of the drug in patients once they are afflicted with adverse side effects. ¶62.

Moreover, safety concerns related to Risperdal Consta, including cerebrovascular effects in elderly patients, extrapyramidal symptoms, QT interval prolongation and diabetes, went unreported to worldwide regulatory authorities for long periods, in some cases for studies completed well before the beginning of the Class Period, and negatively impacted the regulatory review process. ¶¶7, 71-82. Defendants knew that for one or more reasons related to the known but unmet manufacturing, safety or efficacy requirements for the drug, the NDA for Risperdal Consta would not be approved on July 1, 2002. ¶82.

On July 1, 2002, both the Company and Johnson & Johnson issued press releases announcing that Johnson & Johnson had received a non-approvable letter from the FDA for Risperdal Consta. ¶64-65. The Johnson & Johnson press release stated that the FDA had not raised any significant concerns regarding the manufacturing process. ¶65. Defendants themselves failed to note that they were still at the earliest stage of converting their facility into the highly automated commercial manufacturing facility that would be necessary for commercial production. ¶66.

As a result of the July 1, 2002 announcement of a non-approvable letter for Risperdal Consta, Alkermes' stock price dropped over a two-day period from a high of \$16.01 per Share to a low of \$4.04 per share – a drop of over 74%. ¶67.

## III. PROCEDURAL BACKGROUND

The *Bennett* action was filed on October 29, 2003. Pursuant to §21D(a)(3)(A)(i) of the Exchange Act, the plaintiff in *Bennett* published the required early notice to class members on October 29, 2003, on *Business Wire*, whereby he advised those who purchased or otherwise acquired Alkermes securities of the *Bennett* class action. *See* Affidavit of Nancy Gans ("Gans Aff."), Ex. A.

Thus, the notice requirement of the PSLRA was satisfied. *Greebel v. FTP Software, Inc.*, 939 F. Supp. 57, 62-64 (D. Mass. 1996).

The Exchange Act, as amended by the PSLRA, requires early notice to advise class members of their right to move this Court to be appointed lead plaintiffs within 60 days of publication. Movant has filed this motion prior to the expiration of the 60-day period from the publication of the *Bennett* notice. Further, §21D(a)(3)(B) requires the Court to decide this motion (a) within 90 days from the date of early notice publication; or (b) as soon as practicable after deciding plaintiff's Motion to Consolidate Cases for All Purposes filed concurrently with this motion, whichever is later.

#### IV. ARGUMENT

## A. Movant Is the Most Adequate Plaintiff Under the Exchange Act

1. Movant Has the Largest Financial Interest in the Related Actions

The "most adequate plaintiff" provision of the PSLRA provides that a court

shall appoint as lead plaintiff the member or members of the purported plaintiff class that the court determines to be most capable of adequately representing the interests of class members (hereafter in this paragraph referred to as the "most adequate plaintiff") in accordance with this subparagraph.

Section 21D(a)(3)(B)(i), 15 U.S.C. §78u-4(a)(3)(B)(i). Moreover, the Exchange Act, as amended by the PSLRA, requires a court to adopt a rebuttable presumption

that the most adequate plaintiff in any private action arising under this chapter is the person or group of persons that --

\* \* \*

b. in the determination of the court, has the largest financial interest in the relief sought by the class ....

Section 21D(a)(3)(B)(iii)(I), 15 U.S.C. §78u-4(a)(3)(B)(iii)(I). *In re Cavanaugh*, 306 F.3d 726 (9th Cir. 2002) (holding that the proposed lead plaintiff with the largest financial interest is the presumptive lead plaintiff).

Congress enacted the PSLRA and these provisions to encourage and induce institutional investors like Movant to step forward and assume the role of lead plaintiff. See, e.g., Greebel, 939 F. Supp. at 63 (PSLRA "suggest[s] a presumption that institutional investors be appointed lead plaintiff ... "); In re Lucent Techs. Inc. Secs. Litig., 194 F.R.D. 137, 152 (D.N.J. 2000) (appointment of pension trust fund as lead plaintiff was "consistent with the PSLRA," citing excerpts from the legislative history regarding the appointment of institutional investors); In re McKesson HBOC, Inc. Secs. Litig., 97 F. Supp. 2d 993, 997 (N.D. Cal. 1999) ("[w]hen discussing this language, the Congressional drafters focused on their desire to have institutional investors take charge of securities litigation, rather than on how to determine the 'greatest financial interest'") (citation omitted); Gluck v. CellStar Corp., 976 F. Supp. 542, 548 (N.D. Tex. 1997) ("through the PSLRA, Congress has unequivocally expressed its preference for securities fraud litigation to be directed by large institutional investors"). As a sophisticated institutional investor who is ready to take a lead role and direct the progress of the present securities litigation, Movant fulfills these requirements.

During the Class Period, Movant purchased on the open market or otherwise acquired Alkermes securities at prices artificially inflated by defendants' false and misleading statements and has suffered approximately \$88,388 in losses from those purchases. Movant believes it has the largest financial interest in the outcome of this litigation and, therefore, is presumptively entitled to the presumption of "most adequate plaintiff." *Greebel*, 939 F. Supp. at 64-65; 15 U.S.C. §§78u-4(a)(3)(B)(iii)(I)(bb), 77z-1(a)(3)(B)(iii)(I)(bb).

In addition, Movant has selected and retained counsel highly experienced in prosecuting securities class actions such as this to represent it. *See* the firm résumés of Milberg Weiss and Moulton & Gans, attached as Exs. B-C to the Gans Aff.

Therefore, the Proposed lead plaintiff satisfies the prerequisites for appointment as lead plaintiff pursuant to §21D(a)(3)(B).

#### 2. Movant Is Qualified Under Rule 23

Section 21D(a)(3)(B)(iii)(I)(cc) of the Exchange Act further provides that, in addition to possessing the largest financial interest in the outcome of the litigation, the lead plaintiff or plaintiffs must also "otherwise satisf[y] the requirements of Rule 23 of the Federal Rules of Civil Procedure." With respect to the qualifications of the class representative, Rule 23(a) requires that the claims be typical of the claims of the class and that the representative will fairly and adequately protect the interests of the class.

As detailed below, Movant satisfies the typicality and adequacy requirements of Rule 23(a), thereby justifying the appointment of Movant as lead plaintiff.

## a. Movant's Claims Are Typical of the Claims of the Class

The typicality requirement of Rule 23(a)(3) is satisfied when the named plaintiffs have: (a) suffered the same injuries as the absent class members; (b) as a result of the same course of conduct by defendants; and (c) their claims are based on the same legal issues. *Milonas v. Williams*, 691 F.2d 931, 938 (10th Cir. 1982); *Kinney v. Metro Global Media, Inc.*, C.A. No. 99-579 ML, 2002 U.S. Dist. LEXIS 18628, at \*6 (D.R.I. Aug. 22, 2002); *In re Bank of Boston Corp. Sec. Litig.*, 762 F. Supp. 1525, 1532 (D. Mass. 1991); *Shields v. Smith*, No. C-90-0349 FMS, 1992 U.S. Dist. LEXIS 15718, at \*\*12-16 (N.D. Cal. Aug. 14, 1992).

Case law also establishes that "the burden on plaintiffs in proving typicality is not 'very substantial." *Abelson v. Strong*, Civil Action No. 85-0592-S, 1987 U.S. Dist. LEXIS 7515, at \*8 (D. Mass. July 30, 1987) (citation omitted). As Judge Keeton explained:

In order to meet the typicality requirement of Rule 23(a)(3) "plaintiffs need not show substantial identity between their claims and those of absent class members, but need only show that their claims arise from the same course of conduct that gave rise to

the claims of absent members. The question is simply whether a named plaintiff, in presenting his case, will necessarily present the claims of the absent plaintiffs."

Randle v. SpecTran, 129 F.R.D. 386, 391 (D. Mass. 1988) (citing Priest v. Zayre Corp., 118 F.R.D. 552, 554 (D. Mass. 1988)).

The questions of law and fact common to the members of the class which predominate over questions which may affect individual class members include the following:

- (a) Whether the federal securities laws were violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants knew, had reason to know or recklessly disregarded that their statements were false and misleading or failed to have a reasonable basis for those statements;
- (d) Whether the price of Alkermes stock was artificially inflated during the Class Period; and
- (e) The extent of damage sustained by class members and the appropriate measure of damages.

There is a well-defined community of interest in the questions of law and fact involved in this case. Thus, the claims asserted by the Proposed Lead Plaintiff are typical of the claims of the members of the proposed class. Movant alleges, as do the members of the class, that defendants violated the Exchange Act by publicly disseminating a series of false and misleading statements about Alkermes during the Class Period. Movant acquired Alkermes securities at prices inflated by defendants' misrepresentations and omissions and was damaged thereby. Typicality exists here because the claims asserted by Movant are based on the same legal theory and arise "from the same events or course of conduct as do the injuries that form the basis of the class claims." *Bank of Boston*, 762 F. Supp. at 1532; *accord Blackie v. Barrack*, 524 F.2d 891, 902-03 & n.19 (9th Cir. 1975).

## b. The Proposed Lead Plaintiff Will Fairly and Adequately Represent the Interests of the Class

In *Adair v. Sorenson*, 134 F.R.D. 13 (D. Mass. 1991), the Court summarized the adequacy of representation test of Rule 23(a)(4) as follows:

"The 'two basic guidelines for meeting the adequacy of representation standard of Rule 23(a)(4) are: (1) the absence of potential conflict between the named plaintiff and the class members and (2) that counsel chosen by the representative parties is qualified, experienced and able to vigorously conduct the proposed litigation."

Id. at \*18 (quoting Andrews v. Bechtel Power Corp., 780 F.2d 124, 130 (1st Cir. 1985)).

Movant satisfies this two-part test. There is no potential conflict between Movant and the class as all are aligned in the common interest of recovering their damages from defendants. As detailed above, Movant shares substantially similar questions of law and fact with the members of the proposed class, and its claims are typical of the members of the class. Movant has amply demonstrated its adequacy as class representative by signing a certification, filed with the Court, affirming its willingness to serve as and assume the responsibilities of class representative. Gans Aff., Ex. D. In addition, Movant has selected counsel highly experienced in prosecuting securities class actions to represent it. Gans Aff., Exs. B-C. The firms will vigorously prosecute this litigation on behalf of the class.

Accordingly, the Proposed Lead Plaintiff meets the requirements of §21D(a)(3)(B)(iii)(I)(cc) of the Exchange Act and should be appointed lead plaintiff.

## B. This Court Should Approve Movant's Choice of Lead Counsel

The PSLRA vests authority in the lead plaintiffs to select and retain lead counsel, subject to court approval. See §21D(a)(3)(B)(v). Thus, the court should not disturb the lead plaintiffs' choice of counsel unless "necessary to protect the interests of the plaintiff class." See 141 Cong. Rec. H13700 (daily ed. Nov. 28, 1995). Movant has selected Patrick J. Coughlin and Jeffrey W. Lawrence of Milberg Weiss to serve as lead counsel and Moulton & Gans to serve as liaison

counsel. These attorneys and their firms possess extensive experience in the area of securities litigation and have successfully prosecuted numerous securities fraud class actions on behalf of injured investors. *See* Gans Aff., Exs. B-C. Thus, the Court may be assured that, in the event the instant motion is granted, the members of the class will receive the highest caliber of legal representation available.

#### V. CONCLUSION

For all the foregoing reasons, Movant respectfully requests that the Court: (a) appoint it as lead plaintiff in the above-captioned actions, pursuant to §21D(a)(3)(B) and (b) approve its choice of Patrick J. Coughlin and Jeffrey W. Lawrence of Milberg Weiss as lead counsel and Moulton & Gans as liaison counsel for the class.

DATED: December 29, 2003

Respectfully submitted,

MOULTON & GANS, P.C.

CERTIFICATE OF SERVICE

hereby certify that a true copy of the above document was served upon the attorney of record, for each party

by mail (by hand) on \_/2/29/0

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